

REMARKS

Reconsideration of this application is respectfully requested. Claims 1 and 56 have been amended to recite that the solid pharmaceutical composition is in particulate form. Support for this amendment is found at, for example, claim 21. Claims 1, 3-5, and 56 have been amended as discussed below. Claim 21 has been canceled without prejudice. Claims 22 and 23 have been amended to depend from claim 1 rather than canceled claim 21. Claims 1, 3-10, 16-20, 22-29, 31-34, 36-44 and 51-57 are pending and at issue.

Petition to Correct Inventorship

Submitted herewith is a Petition under 37 C.F.R. § 1.48(b) to remove Tomas Norling as a named inventor of the above-identified application. Upon the granting of this Petition, Per Holm will be the sole inventor of the present application.

Indefiniteness Rejection

Claims 1, 3-10, 16-29, 31-34, 36-44, and 51-57 have been rejected as indefinite.

According to the Examiner, there is insufficient antecedent basis for the term “active ingredient” in claims 1, 3, 4, and 56 and the term “vehicle” in claims 3-5. The term “active ingredient” in these claims has been replaced with the term “tacrolimus.” The term “vehicle” in claims 3-5 has been replaced with “the polyethylene glycol and the poloxamer.”

According to the Examiner, it is unclear whether only the poloxamer or all of the tacrolimus, polyethylene glycol, and poloxamer are on a solid carrier. Claim 1 has been amended to clarify that “the tacrolimus, polyethylene glycol and poloxamer are on a solid carrier.”

For the reasons discussed above, Applicant respectfully requests withdrawal of this rejection.

Written Description Rejection

Claims 1, 3-10, 16-29, 31-34, 36-44, and 51-57 have been rejected for failing to comply with the written description requirement. Specifically, the Examiner contends that claim 1 “can reasonably be interpreted as being drawn to a composition comprising tacrolimus in polyethylene glycol, in combination with a poloxamer on a solid carrier,” which he argues is not supported by the original disclosure. The Examiner, however, acknowledges that the “Specification as originally filed has adequate written description for a composition comprising tacrolimus dissolved or dispersed in polyethylene glycol, combined with a poloxamer, and [the] combination applied on a solid carrier to obtain the solid pharmaceutical composition” (March 31, 2010 Office Action, p. 4-5).

As discussed above, claim 1 has been amended to recite that the tacrolimus, polyethylene glycol, and poloxamer are on a solid carrier. Accordingly, Applicant respectfully submits that the claims are properly supported by the specification. Withdrawal of this rejection is respectfully requested.

Obviousness Rejection Over Koretke in view of Drugs.Com

Claims 1, 3-10, 16-20, 24-26, 31-34, 38-44, and 56 have been rejected as obvious over Koretke (WO 01/95939) in view of Drugs.Com (“Tacrolimus (Systemic)”, Drugs.com, August 1997).

Independent claims 1 and 56 have been amended to incorporate the limitation of claim 21 (i.e., to recite that the solid pharmaceutical is in particulate form) which has not been rejected

over Koretke and Drugs.com. Accordingly, Applicant respectfully requests withdrawal of this rejection.

Obviousness Rejection Over Holm in view of Drugs.Com

Claims 1, 3-10, 16-29, 31-34, 36-44, and 51-57 have been rejected as obvious over WO '001 (WO 03/04001) in view of Drugs.Com.

Applicant respectfully traverses this rejection, and request reconsideration.

WO '001 was published on January 16, 2003, less than one year before the effective filing date of the present application. The present application claims priority to U.S. provisional application no. 60/529,793, filed December 15, 2003. Accordingly, WO '001 is not available as a prior art reference under 35 U.S.C. §102(b) to the present application.

Submitted herewith is a Declaration under 37 C.F.R § 1.132 of Per Holm, the sole inventor of the presently claimed invention. Dr. Holm is also one of the named inventors of WO '001. In the Declaration, Dr. Holm states that the disclosure in WO '001 of compositions containing a combination of polyethylene glycol and a poloxamer is his own work, and not the work of others (Holm Decl., ¶7 and 8). Dr. Holm further states that he is the sole inventor of the presently claimed compositions containing a combination of polyethylene glycol and a poloxamer (Holm Decl., ¶2 and 3).

Thus, WO '001 describes Applicant's own work. Accordingly, WO '001 is not available as a reference under 35 U.S.C. §102(a) or (e). Applicant, therefore, respectfully requests withdrawal of this rejection.

Provisional Obviousness-type Double Patenting Rejection

Claims 1, 3-11, 13-29, 31-34, 36, 37, 40-44, and 51-56 have been provisionally rejected for obviousness-type double patenting over claims 1-10, 20-25, 27-29, 31-37, 40-44, 51, and 52 of U.S. Patent Application No. 10/569,862. In order to expedite prosecution of this application, submitted herewith is a terminal disclaimer over U.S. Patent Application No. 10/569,862. Accordingly, Applicant respectfully requests withdrawal of this provisional rejection.

In view of the above amendments and remarks, Applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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